

Notice of Allowability

Application No.

09/521,524

Examiner

Shanon Foley

Applicant(s)

DAVIDSON ET AL.

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1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 4/23/4.
2. ☒ The allowed claim(s) is/are 45-53 and 59-67.
3. ☒ The drawings filed on 08 March 2000 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit
of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413),
Paper No./Mail Date _____
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Ann Viksnins on June 30, 2004.

The application has been amended as follows:

Claims 54-58 have been cancelled.

Reasons for Allowance

The following is an examiner's statement of reasons for allowance:

Applicant has submitted Declarations that Evidence that Aoki et al. is not applicable as prior art.

The prior art does not teach or suggest a cloning system, a host cell or a method of producing a recombinant adenovirus with

- (a) an Ad backbone plasmid comprising an Ad genome lacking map units 0 to 9.2, and
- (b) a shuttle plasmid comprising Ad sequences from 0 to 1 and 9.2 to 16.1 map units of an Ad genome.

Herlyn et al. (WO 98/39035) teach a shuttle plasmid comprising Ad sequences from 0 to 1 and 9.2 to 16.1 map units. However, the backbone of Herlyn et al. comprise map units 2-100,

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see Figures 1 and 3 as well as page 21, line 27 to page 22, line 4. Herlyn et al. do not teach or suggest deleting more map units in the backbone plasmid.

Wilson et al. (US 6,251,957) teach a shuttle plasmid comprising sequences from 0 to 1 and 9.2 to 16. There is no teaching or suggestion in Wilson et al. to substitute 16.1 map units in the shuttle plasmid instead of 16. This shuttle is co-transfected into 293 cells with sub360 DNA, which is derived from adenovirus type 5 sequences. Wilson et al. do not teach or suggest a adenovirus backbone lacking the required instant map units.

Wilson et al. (US 6,251,677) teach a shuttle plasmid comprising map units 0-1 and 9-16. However, the instant shuttle plasmid comprises 0-1 and 9.2-16.1 map units. There is no teaching or suggestion in Wilson et al. to incorporate 9.2 to 16.1 map units into the shuttle plasmid. Further, the backbone of Wilson et al. comprises 2 to 100 map units. See Figure 1C. This is in contrast to the instant backbone lacking map units 0-9.2.

Davidson et al. (US 5,747,072) teach a shuttle plasmid comprising 0-1 and 9.2-16.1 map units, see Figure 2 and column 8, line 50 to column 9, line 2. This plasmid is combined with an adenovirus genome lacking E1 sequences, see column 9, line 54 to column 10, line 1. Davidson et al. do not teach or suggest using an adenovirus backbone plasmid lacking map units 0 to 9.2.

Finally, the teachings of Stratford-Perricaudet et al. (Journal of Clinical Investigation. 1992; 90: 626-630) are drawn to generating a recombinant adenovirus by homologous recombination with a plasmid comprising 0-1.3 and 9.4-17 map units and an adenovirus backbone comprising 2.6-100 map units, see Figure 1 and the first two paragraphs of the "Methods" section on page 626. Stratford-Perricaudet et al. do not teach or suggest generating a

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recombinant adenovirus with the shuttle and backbone plasmids comprising the instant map units.

None of the closest prior art cited teaches or suggests a recombinant technique for generating a recombinant adenovirus with a shuttle plasmid comprising map units 0-1 and 9.2-16.1 and a backbone plasmid lacking map units 0-9.2. In other words, the prior art does not teach or suggest a backbone plasmid that lacks the region from the lefthand ITR to the portion of adenoviral sequence that is also present in the shuttle plasmid.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shanon Foley whose telephone number is (571) 272-0898. The examiner can normally be reached on M-F 9:30 AM - 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (571) 272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

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system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Shanon Foley